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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,345	12/01/2003	Johanna G. H. Ruseler-van Embden	2183-6192US	5255

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TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER

AFREMOVA, VERA

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/727,345	Applicant(s) RUSELER-VAN EMBDEN ET AL.	
	Examiner Vera Afremova	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 20-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/01/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 20-26 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention(s). A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-19 as amended (7/05/2006) are under examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in EPO on 5/20/1998. It is noted, however, that applicant has not filed a certified copy of the EPO application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

The information disclosure statement filed 12/01/2003 has been fully considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3 and 5-19 as amended are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,906,457 (Ryan) in the light of evidence by Pearce et al. (IDS reference; Archives of Biochemistry and Biophysics. 1982, Vol. 213, No. 2, pages 456-462).

Claims are directed to a skin care or topical pharmaceutical composition comprising 1) a proteolytic activity inhibitor derived from potato that contains trypsin inhibitor and elastase

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inhibitor and 2) a cosmetically or pharmaceutically acceptable vehicle. Some claims are further drawn to the use of the inhibitor in amounts 1-20 % (wt/wt). Some claims are further drawn to the vehicle being in form of lotion, gel or aqueous solution, etc. Some claims are further drawn to the use of additional materials including adjuvant and some generic emollients, thickeners, preservatives and water. Some claims are further drawn to the composition being incorporated into various articles including wipe, cloth or dispenser.

US 4,906,457 (Ryan) discloses a skin care or topical pharmaceutical composition comprising an inhibitor of proteolytic activity that is derived from potato and a cosmetically or pharmaceutically acceptable vehicle (col. 3, lines 58-65). In particular, the composition comprises potato derived protease inhibitor in amounts about 0.01%, glycerol and water (example 1). The potato inhibitor I is a protease inhibitor, thus, it is inherently characterized by activity against proteases including trypsin and elastase as evidenced by the IDS reference by Pearce et al., for example: see abstract. The cited patent teaches the use of protease inhibitor in amounts approximately 10 mg/ml or higher in the topical composition (col. 2, line 24) or the use of protease inhibitor in desired proportions (col. 3, line 33). The composition is in a form of lotion, gel or aqueous solution, etc (example 1 or col. 2, lines 35-40) and contains additional generic materials suitable as generic emollients, thickeners, and preservatives within generic meaning of "emollients", "thickeners" and "preservatives" of the claims 9-11. The composition with protease inhibitor is applied to the skin, it is incorporated into various articles of manufacture including brush, wipe, etc. (col. 3, line 55) and the aqueous composition with protease inhibitor is provided in containers or dispenser within the broadest meaning of the

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claims 7, 8, 13-19. The particular composition of example 3 contains more than 50% of water within the broadest meaning of "Lanette cream" of the claim 12.

Thus, the composition of US 4,906,457 (Ryan) is identical to the claimed composition and, therefore, US 4,906,457 (Ryan) anticipates the claimed invention.

2. Claims 1-3 and 5-19 as amended are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,950,509 (Geks et al) in the light of evidence by Pearce et al. (IDS reference; Archives of Biochemistry and Biophysics. 1982, Vol. 213, No. 2, pages 456-462).

Claims as above.

US 3,950,509 (Geks et al) discloses a skin care or topical composition comprising a cosmetically or pharmaceutically acceptable vehicle and a proteolytic activity inhibitor derived from potato (examples 3-4 at col. 3, line 32 and line 40; col. 4, line 1 and line 19) including kallikren-trypsin inhibitor derived from potatoes (col. 2, line 5 and example 1). The potato inhibitor is a protease inhibitor, thus, it is inherently characterized by activity against proteases including trypsin and elastase as evidenced by the IDS reference by Pearce et al., for example: see abstract. The potato-derived inhibitor is present in amounts from 1.5 wt. % (col. 2, line 54; col. 3, line 3) to about 3 wt. The composition is in a form of lotion, gel or aqueous solution, etc (col. 2, lines 25-27; examples 1 and 2) and contains additional generic materials suitable as generic emollients, thickeners, preservatives (see examples 1-4) within generic meaning of "emollients", "thickeners" and "preservatives" of the claims 9-11. The composition with protease inhibitor is applied to the skin, it is incorporated into various articles of manufacture including cloth (col. 3, line 5) and the aqueous composition with protease inhibitor is provided

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in containers or dispenser within the broadest meaning of the claims 7, 8, 13-19. The composition of example 2 contains more than 50% of water within the broadest meaning of "Lanette cream" of the claim 12.

Thus, the composition of US 3,950,509 (Geks et al) is identical to the claimed composition and, therefore, US 3,950,509 (Geks et al) anticipates the claimed invention.

3. Claims 1, 2, 4, 5, 6, 8, 12 and 13 as amended are rejected under 35 U.S.C. 102(b) as being anticipated by Rodis et al ("Naturally occurring protein crystals in the potato". Plant Physiol. 1984, 74:907-911) in the light of evidence by Pearce et al. (IDS reference; Archives of Biochemistry and Biophysics. 1982, Vol. 213, No. 2, pages 456-462).

Claims are directed to a composition comprising 1) a proteolytic activity inhibitor derived from potato that contains trypsin inhibitor and elastase inhibitor and 2) a cosmetically or pharmaceutically acceptable vehicle. Some claims are further drawn to the composition pH of 4.8-5.5. Some claims are further drawn to the vehicle being in form of aqueous solution or solution that can be absorbed into wipe, sheet, etc. Some claims are further drawn to the composition with 50% water and more.

The cited reference by Rodis et al discloses a composition comprising a proteolytic activity inhibitor derived from potato and a cosmetically or pharmaceutically acceptable vehicle such as sodium acetate buffer, for example: see page 909, col. 2, last par., lines 1-2. The potato inhibitor is a protease inhibitor, thus, it is inherently characterized by activity against proteases including trypsin and elastase as evidenced by the IDS reference by Pearce et al., for example: see abstract. The particular composition has pH of about 4-5. The cited reference also teaches

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that potato-derived proteins such as inhibitors of proteolytic activity are readily dissolved at pH 4-5. The aqueous solution(s) can be absorbed into wipe, sheet, etc and they contain 50% water and more within the broadest meaning of the claims 2, 5, 6, 8, 12 and 13.

Thus, the composition of the cited reference by Rodis et al is identical to the claimed composition and, therefore, the cited reference by Rodis et al anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,906,457 (Ryan) and US 3,950,509 (Geks et al) taken with Rodis et al ("Naturally occurring protein crystals in the potato". Plant Physiol. 1984, 74:907-911) and Pearce et al. (IDS reference; Archives of Biochemistry and Biophysics. 1982, Vol. 213, No. 2, pages 456-462).

Claims are directed to a skin care or topical pharmaceutical composition comprising a proteolytic activity inhibitor derived from potato and a cosmetically or pharmaceutically acceptable vehicle. Some claims are further drawn to the use of the inhibitor in amounts 1-20 % (wt/wt). Some claims are further drawn to the composition pH of 4.8-5.5. Some claims are further drawn to the vehicle being in form of lotion, gel or aqueous solution, etc. Some claims are further drawn to the use of additional materials including adjuvant and some generic

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emollients, thickeners, preservatives and water. Some claims are further drawn to the composition being incorporated into various articles including wipe, cloth or dispenser.

US 4,906,457 (Ryan) and US 3,950,509 (Geks et al) are relied upon as explained above for the disclosure of a skin care or topical pharmaceutical composition comprising a proteolytic activity inhibitor derived from potato and a cosmetically or pharmaceutically acceptable vehicle. The potato inhibitor is a protease inhibitor, thus, it is inherently characterized by activity against proteases including trypsin and elastase as evidenced by the IDS reference by Pearce et al., for example: see abstract. Some of the cited compositions comprise potato protease inhibitor in amounts within the presently ranges. The cited references also teach and suggest that the amounts of active ingredients and genetic carriers can be adjusted as desired to provide for compositions in various forms.

The cited patents are silent about pH of the compositions with potato protease inhibitors. However, the reference by Rodis et al teaches that potato protease inhibitors are readily dissolved at pH 4-5 unlike neutral or alkaline pH.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use acidic pH in topical compositions of US 4,906,457 (Ryan) and US 3,950,509 (Geks et al) with a reasonable expectation of success in dissolving active ingredients such as potato-derived protease inhibitors. One of skill in the art would have been motivated to use acidic pH for making aqueous compositions with potato-derived protease inhibitors for the expected benefits in fully dissolving active ingredients and, thus, maximizing delivery of the active ingredients to the desired target under treatment or to absorbing materials.

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Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicant's arguments filed 7/05/2006 have been fully considered but they are not persuasive.

With regard to the claim rejection under 35 U.S.C. 102(b) as being anticipated by US 4,906,457 (Ryan) or by US 3,950,509 (Geks et al) or by Rodis et al. applicants' main argument is directed to the idea that the disclosed compositions do not contain a combination of 2 inhibitors derived from potato including trypsin and elastase inhibitors. Upon review of the cited references it is not found particularly true because the compositions contain a potato-derived inhibitor having a proteolytic activity as a whole product that is inherently characterized by both trypsin and elastase activities in the light of evidence by Pearce et al., for example: see abstract. The applicants' claimed combination of trypsin and elastase inhibitors is not a combination of two separate and purified proteins but it is a whole product with proteolytic activity that is derived from potato and that is characterized by both trypsin and elastase activities (table 7, page 48). Thus, the cited prior art anticipates the applicants' composition as claimed and even when read in the light of specification.

Applicants appears to argue that the prior art US 4,906,457 (Ryan) does not recognize that elastase inhibitor is derived from potato and that the prior art composition has a different

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purpose such as prevention of skin cancer. This argument is not found convincing because at the very least the Ryan's patent teaches the use of elastase in the topical composition for prevention skin cancer composition (col. 4, line 44). Moreover, the "potato inhibitor" is an effective inhibitor of both trypsin and elastase as also evidenced by US 6,180,607 (col. 4, lines 37-38).

In response to applicant's arguments as drawn to the intended use of the cited compositions, it is noted that the cited compositions are skin care compositions within the meaning of the claimed compositions. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

N claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

September 14, 2006



VERA AFREMOVA

PRIMARY EXAMINER